DEPARTMENT OF HEALTH AND HUMAN SERVICES

95052d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 22, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-04

David B. Ryan, President,
Hood River Juice Co., Inc.
1590 Country Club Road
Hood River, Oregon 97031

WARNING LETTER

Dear Mr. Ryan:

We inspected your firm, Hood River Juice Company Inc., located at 1590 Country Club Road, Hood River, Oregon, on July 14, 15, 19, and 20, 2004, and found that you have serious deviations from the Juice Hazard Analysis Critical Control Point (HACCP) regulation (21 CFR Part 120). Failure of a processor to have and to implement a HACCP system that complies with 21 CFR 120.6, 120.7 and 120.8, or otherwise to operate in accordance with the requirements of this part, shall render the juice products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act). The deviations cause your 100% apple juice, your 100% pear juice, and your blend of 100% apple juice and pear juice to be in violation of section 402(a)(4) of the Act. You can find the Act and the juice HACCP regulation through links in FDA's home page at www.fda.gov. Your firm is classified as a small business and therefore you were to be in compliance with this regulation by January 21, 2003, as set out in 21 C.F.R. § 120.1.

The serious deviations were as follows:

1. You must have records documenting your HACCP system, to comply with 21 CFR 120.12(a)(4)(i). However, your firm does not maintain records documenting the monitoring of the patulin hazard at the "Sorting" critical control point (CCP) for the 100% apple juice and the blend of 100% apple juice and pear juice. Patulin is a toxic substance produced by molds that grow on apples.

2. You must monitor conditions and practices during processing with sufficient frequency to ensure conformance with the current good manufacturing practice regulation, to comply with 21 CFR 120.6(b). However, your firm did not monitor prevention of cross contamination from insanitary objects to food, including gloves and outer garments and protection of food from adulteration with sufficient frequency, as evidenced by:

   - An employee who, on July 14, 2004, used her gloved hands to remove waste material from the floor and then handled apples on the sorting table without cleaning and sanitizing her hands and gloves.

   - An employee in the processing room used a shovel to scoop apples from the floor and dump them into an apple flue immediately prior to the table sorting.

3. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 120.6(c). However, your firm does not maintain sanitation control records documenting the prevention of cross contamination from insanitary objects; the maintenance of hand washing facilities and toilet facilities; the protection of food packaging materials from adulteration; proper labeling, storage, and use of toxic compounds; and control of employee health conditions.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

It is essential that you respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plans for your 100% juice products, copies of Sanitation Standard Operating Procedure records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the HACCP regulation, and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations. Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE,

Bothell, WA 98021-4421. If you have questions regarding any issue in this letter, please contact Michael J. Donovan at (425) 483-4906.

Sincerely,

Charles M. Breen
District Director

Enclosure:
Form FDA 483

cc: OSDA, with disclosure statement